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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,539	04/28/2000	Roy Curtiss III	3116-4355	3756

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 11/20/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/560,539</b>	Applicant(s) <b>Curtiss III</b>	
	Examiner <b>Portner</b>	Art Unit <b>1645</b>	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
<b>Period for Reply</b>			
<p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>1</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p>			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
<p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Sep 6, 2001</u></p>			
<p>2a) <input type="checkbox"/> This action is <b>FINAL</b>.</p>		<p>2b) <input checked="" type="checkbox"/> This action is non-final.</p>	
<p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>			
<b>Disposition of Claims</b>			
<p>4) <input checked="" type="checkbox"/> Claim(s) <u>2-8, 12-22, and 32-37</u> is/are pending in the application.</p>			
<p>4a) Of the above, claim(s) _____ is/are withdrawn from consideration.</p>			
<p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p>			
<p>6) <input type="checkbox"/> Claim(s) _____ is/are rejected.</p>			
<p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p>			
<p>8) <input checked="" type="checkbox"/> Claims <u>2-8, 12-22, and 32-37</u> are subject to restriction and/or election requirement.</p>			
<b>Application Papers</b>			
<p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p>			
<p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.</p>			
<p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved.</p>			
<p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>			
<b>Priority under 35 U.S.C. § 119</b>			
<p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).</p>			
<p>a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p>			
<p>1. <input type="checkbox"/> Certified copies of the priority documents have been received.</p>			
<p>2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</p>			
<p>3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p>			
<p>*See the attached detailed Office action for a list of the certified copies not received.</p>			
<p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).</p>			
<b>Attachment(s)</b>			
<p>15) <input type="checkbox"/> Notice of References Cited (PTO-892)</p>		<p>18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p>	
<p>16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p>		<p>19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p>	
<p>17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____</p>		<p>20) <input type="checkbox"/> Other: _____</p>	

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**DETAILED ACTION**

Claims 1, 9-11, 23-31 and 38 have been canceled.

Claims 2-8, 12-22, 32-37 are pending and under consideration.

**Please Note:**

The previous Election/Restriction made of record in paper number 10, is herein vacated in light of Applicant's arguments and the examiner's realization that the species set forth in the prior Election/Restriction were not clear, wherein a single combination for each of the reagents in the independent claim should have been elected. The requirement was not based upon the reagents set forth in the generic claims. The following Election/Restriction will address this requirement.

***Election/Restriction***

1. Claims 2-8, 12-22 and 32-37, drawn to a microorganism, a vector, first control sequence, second control sequence, an activate able control sequence, a first origin of replication, a second origin of replication, a first repressor, a gene that encodes a desired product classified in class 435, subclass 69.3.
2. This application contains claims directed to the following patentably distinct species of the claimed invention: Applicant is requested to elect a single species for each of the reagents recited in the independent claim that evidences original descriptive support and is taught to be an embodiment within the scope of the claimed invention disclosed in the instant specification:

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**Microorganism:**

I. Viruses

II. Protozoa

III. Unicellular fungi

IV. Bacteria:

V. Runaway vector (claim 21)

**Vector:**

plasmid (page 15, lines 23-28 and page 17, lines 17-26)

**First Control sequence:**

P22Pr, mal, lac, tac, cspA, phoA,  $P_{bad}$  (araCPbad), trc,  $\lambda$ PL, eukaryotic, luxI, lasB, traA, tral(page 24, lines 15-16), virB (page 25, line 20),

**Second Control sequence:**

P22Pr, mal, lac, tac, cspA, phoA,  $P_{bad}$  (araCPbad), trc,  $\lambda$ PL, eukaryotic, luxI, lasB, traA, tral(page 24, lines 15-16), virB (page 25, line 20)

**First Activate able Control (inducer) sequence:**

P22Pr, mal, lac, tac, cspA, phoA,  $P_{bad}$  (araCPbad), trc,  $\lambda$ PL, eukaryotic,

**First Repressor sequence:**

malT(page 27, line 18), LacI, C2, C22 (page 19, lines 25-26),  $P_R$ ,  $P_{trc}$ , araCP<sub>BAD</sub>, C1857 (page 26, line 9)

**First origin of replication:**

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pSC ori, pUC ori.

**Second origin of replication:**

pSC ori, pUC ori

**Other optional elections recited generically in dependent claims:**

3. Claim 6 broadly recites the term attenuated. If attenuated elected ~~A~~ a specific mutation to attenuate:

$\Delta$ end	$\Delta$ hemA	$\Delta$ DAP (page 4, instant specification, bacteria)	$\Delta$ galR
$\Delta$ cya	$\Delta$ aroA	$\Delta$ rpoS (page 5, instant specification, bacteria)	$\Delta$ Acdt
$\Delta$ crp	$\Delta$ aroC	$\Delta$ asd (page 6, instant specification, bacteria)	
$\Delta$ phoPQ	$\Delta$ aroD	$\Delta$ araCBAD (page 11, instant specification)	
$\Delta$ ompR	$\Delta$ hrtA	$\Delta$ araE (page 11, instant specification)	
$\Delta$ galE (page 4, instant specification, bacteria)			

4. Claim 22 defines the type of expression the microorganism will have:

- A. high copy number
- B. low copy number
- C. delayed expression of antigen

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 2-4, 6, 19, and 22 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

November 14, 2001

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600